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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,460	09/11/2003	Robert Boock	022956-0223	7148

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/661,460	Applicant(s) BOOCK ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/11/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, drawn to an apparatus, classified in class 600, subclass 564.
 - II. Claims 26-30, drawn to a process, classified in class 600, subclass 564.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed requires a materially different apparatus as claimed further comprising a tissue scaffold.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Lisa Michaud on 12/01/05 a provisional election was made without traverse to prosecute invention I: drawn to an apparatus, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement(s) (IDS) submitted on 10/02/2003 and 03/14/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Drawings

7. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because dark photographs are not permitted. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 10-11, 21-22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman et al (WO 99/58066). Altman discloses an outer tube 14 with an

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open distal end, a shaft 12 disposed within said outer tube articulating between a first, proximal and second, distal positions exposing the distal end of the shaft from the outer tube, a tissue harvesting tip 50 disposed on the distal end of said shaft, and cutting members 13,30,35 coupled to said shaft proximal to the tissue harvesting tip.

10. For claims 2-3, Altman discloses biasing element 65 biasing the shaft proximally and a trigger mechanism 53 connected to a shaft 55 that overcome said biasing elements. For claims 10-11, Altman discloses curved cutting members 30 disposed radially from the shaft (page 10 lines 4-7). For claim 21, Altman discloses a motor 24, typically electric or pneumatic, coupled to the shaft and inherently capable of rotating at speeds ranging from about 100 to 5000 rpm. For claim 22, Altman discloses a harvesting tip 50 extending beyond said outer tube. For claim 25, Altman discloses a vacuum outlet 22 inducing suction in said outer tube and pulling harvested tissue therein.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 4-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Shapira (6358252). Altman discloses the claimed tissue harvesting invention 11 except for the open distal end configured to form a seal with the tissue surface or defined by an angled edge wall further comprising surface features. Shapira teaches a tissue harvesting device 10 comprising an open distal end configured to form a seal with a tissue surface and an angled edge wall including surface features, or ridges 62, as best seen in Figures 2 and 4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Shapira, with Altman for the purpose of increasing the suction force on the cut tissue via a seal drawing the tissue into the device and to break the tissue into smaller pieces with surface ridges on the edge wall.

14. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Thimsen et al (4844064). Altman discloses the claimed tissue harvesting invention 11 except for the open distal end defined by an angled edge wall wherein the angle ranges from 30-75 degrees or is about 40 degrees. Thimsen teaches a tissue-harvesting device 11 comprising an open distal end 16,17 with an angled edge wall equal to about 50 to about 60 degrees (column 2 lines 41-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the tissue harvesting device as taught by Thimsen, with Altman for the purpose of increasing the cutting efficacy of the edge wall of the blade.

15. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Lev (6066153). Altman discloses the claimed tissue harvesting invention 11 except for the harvesting tip configured to comprise either a cone- or semi cylindrical shaped housing with a plurality of cutting disposed thereon and further configured to remove a predetermined volume of tissue. Lev teaches a tissue-harvesting device 10 with various configurations of tissue harvesting tips comprising cone-shaped members and a semi cylindrical-shaped members as seen in Figures 4A and 4B. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Lev, with Altman for the purpose of configuring the tissue harvesting tip for a variety of tissue removal situations.

16. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Lev. Altman discloses the claimed tissue harvesting invention 11 except for the harvesting tip configured to harvest a predetermined volume of tissue when moved from proximal to distal positions. Lev teaches a tissue-harvesting device 10 with various configurations of tissue harvesting tips comprising dimensions inherently capable of harvesting predetermined volumes of tissue ranging from $0.5 - 1.5 \text{ cm}^3$ (column 5 lines 37-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught

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by Lev, with Altman for the purpose of configuring the tissue harvesting tip for extracting a predetermined volume of tissue dependent upon the specific application.

17. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Majlessi (5871454). Altman discloses the claimed tissue harvesting invention 11 except for a sizing screen configured with openings comprising a diameter of 0.7-1.3 mm. Majlessi teaches a tissue-harvesting device 10 with permeable membrane 44" for filtering larger particulate matter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Majlessi, with Altman for the purpose of configuring the tissue harvesting device to filter large application specific particulates.

18. For claims 23-24, Altman discloses the biasing element 65 biasing the shaft proximally and a trigger mechanism 53 connected to a shaft 55 that overcome said biasing elements but does not disclose expressly the biasing distance being 1 to 5 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the tissue extraction device as taught by Altman to bias 1 to 5 mm, because Applicant has not disclosed that a 1 to 5 mm biasing provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the biasing element as taught by Altman, because it provides an identical function and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Altman. Therefore, it would have been an obvious matter of design choice to modify Altman to obtain the invention as specified in the claim(s).

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Conclusion

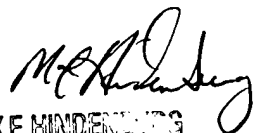
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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